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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/740,824 | 12/21/2000 | Martin Quanz | 215547.01600 | 6581 |

27160 7590 08/01/2003

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EXAMINER

PRATS, FRANCISCO CHANDLER

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1651

DATE MAILED: 08/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/740,824

Applicant(s)

QUANZ ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-23, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 30, 2003, has been entered.

The previously non-entered after-final amendment filed January 30, 2003, has been entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 9-23, 25 and 26 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 14, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations "a purity, in U/ μ g of purified protein, of at least 80%", "a purity, in U/ μ g of purified protein, of at least 90%" and "a purity, in U/ μ g of purified protein, of at least 95%", in claims 14, 25 and 26 as amended are indefinite because it is not clear how pure the enzyme must be.

It is noted that the amended claims now recite the purity in terms of specific activity, and that this activity can be compared to the specific activity of pure amylosucrase. However, as pointed out in the advisory action of February 13, 2003, it is not clear that the specific activity of "pure" amylosucrase is "known." Moreover, applicant has not established for the record what the specific activity of pure amylosucrase is, nor has applicant established whether there is in fact a single art-recognized specific activity for pure amylosucrase. Thus, while the claims as amended now recite the enzyme purity in terms of an ascertainable parameter, the claims as amended still fail to provide a benchmark, i.e. 100% purity, on which the claimed partial percentages are based. Rejection under § 112, second paragraph, remains required.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-15, 20-23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kossman (WO 95/31553) in view of Okada et al (J. Biol. Chem. 249(1):126-135 (1974)) (cited by applicant as reference "AW2" in the information disclosure statement filed December 21, 2000).

Kossman discloses a process of preparing insoluble polysaccharides by contacting sucrose with an amylosucrase under aqueous conditions. See p. 24. Kossman discloses that the

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enzyme should be obtained from the claimed microorganism, *Neisseria polysaccharea* (see p. 5), can be produced recombinantly (see p. 11), can be used in purified form (see p. 24), and can be used in immobilized form (see p. 25). Thus, Kossman differs from the cited claims in that Kossman does not employ the enzyme under buffer-free conditions.

However, Kossman clearly discloses that the enzyme is useful at neutral conditions. See Example 4 at page 35, wherein the enzyme is employed at pH 6.5. Thus, the artisan of ordinary skill, recognizing from Kossman that the enzyme is active at neutral conditions which do not require the addition of a buffer, clearly would have motivated to have omitted the step of adding a buffer to the reaction medium disclosed by Kossman. By omitting the addition of buffer, the artisan of ordinary skill would have made the process easier by omitting a step, and also would have made the process cheaper by omitting the expense of a buffer. Further still, the artisan of ordinary skill clearly had a reasonable expectation that the process would work in the absence of a buffer, based on the fact that the Kossman discloses the enzyme as functioning at neutral conditions.

Kossman also differs from the claims as amended in that Kossman does not disclose that 70% of the sucrose is converted to α -1,4-glucans and fructose within 23.5 hours. However, Okada

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clearly discloses that the claimed enzyme produces an 80% conversion within 2 hours, a time much shorter than that recited in the claims, under the conditions assayed therein. See Fig. 2, page 128, top of right hand column. Thus, the artisan of ordinary skill clearly would have reasonably expected Kossman's process to have yielded a similar conversion, even in the absence of a buffer. In this regard note again that Kossman discloses that the enzyme is active at neutral conditions, and that there is nothing in either Kossman or Okada suggesting that omission of buffer would lower enzyme efficiency. A holding of obviousness is therefore required.

Claims 9-23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kossman (WO 95/31553) in view of Okada et al (J. Biol. Chem. 249(1):126-135 (1974)), as applied to claims 9-15, 20-23, 25 and 26 above, and further in view of Remaud-Simeon (Carbohydrate Bioengineering 1995:313-320).

As discussed above, Kossman renders obvious the process recited in claims 9-15, 20-23, 25 and 26. Kossman differs from the claims in that Kossman does not disclose the addition of a polysaccharide acceptor which may be dextrin, glycogen or amylopectin, as recited in claims 16-19. However, Remaud-Simeon clearly discloses that glycogen, starch (which contains

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amylopectin) and maltooligosaccharides act to activate amylosucrase when they are added to the reaction medium. Thus, the artisan of ordinary skill clearly would have been motivated to have added glycogen and amylopectin to the reaction medium to have afforded the activating effect disclosed by Remaud-Simeon. Moreover, in view of the fact that dextrans are very similar chemically to the compounds disclosed by Remaud-Simeon as having an activating effect on amylosucrase, the artisan of ordinary skill clearly would have had a reasonable expectation that dextrans would have had the same activating effect on amylosucrase as glycogen, starch (which contains amylopectin) and maltooligosaccharides. The artisan of ordinary skill would therefore have been motivated to have added dextrin to the reaction medium used for the production of glucans by amylosucrase, as recited in claims 16-19. A holding of obviousness is therefore clearly required.

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner

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can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
July 31, 2003